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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/266,889	03/12/1999	MICHEL SCHNEIDER	1201-71	6363

7590 02/27/2003

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 02/27/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/266,889

Applicant(s)

SCHNEIDER ET AL.

Examiner

Michael G. Hartley

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/31/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9,14,16,18,19,23 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7,9,14,16,18,19,23 and 27 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Arguments

Any previous rejections, which are not reiterated herein, have been withdrawn.

Applicant asserts that, since the claims were copied from the claims of U.S. patents 5,573,751 and 5,409,688 and the present application has an effective filing date earlier than the patent claims, an interference should be declared.

This is not found persuasive because, as set forth in the office action, the effective filing date of the instant application has not been determined to be the date of the earliest filed application, as stated by applicant. Also, the claims do not appear to be substantially copied from the patents. For example, it is noted that patent '751 has a reexamination certificate issued therein and the '688 claims are drawn to free gasbubbles, and do not recite stabilized microbubbles as instantly claimed. This difference is a critical difference in the definition of the gas bubbles, as free gas bubbles are an important limitation in the patented claims which differentiate over the prior art. The instant claims are not drawn to "free" gas bubbles, but to stabilized gas bubbles which are different. Thus, the instant claims are not substantially copied from the patents, as asserted. Since the prior art encompassed the stabilized gas bubbles as claimed, the claims are not allowable at this time and an interference has not been declared.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the office action mailed 8/7/2002.

Applicant's arguments filed 1/31/2003 have been fully considered but they are not persuasive.

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Applicant asserts that the phrase "an organic compound containing one or more carbon atoms and fluorine" in the claims is described in the specification because this phrase is basically a definition of the term "freon" as described in the specification. This is not found persuasive because this phrase is broader and encompasses more than any dictionary definition of the term freon or general understanding in the art thereof. The term freon is limited to a specific number of gases. Namely, freon is limited to a specific number of gases, usually used as refrigerants, which is a generic term which generally defines a specific set of chlorofluorocarbons or fluorocarbons. However, the definition of "an organic compound containing one or more carbon atoms and fluorine" encompasses any compound having at least one carbon and fluorine, which would include those including nitrogen, oxygen, or any other organic moiety. Clearly, such was not described in the specification at the time of filing. Applicant envisioned the use of freon gas, which is generic term for some known chlorofluorocarbons and fluorocarbons, but there is nothing in the specification to show support for the broad terminology now recited. Dependent claim 9 falls therewith.

Applicant argues that the determination of the effective filing date as set forth by the examiner in the office action mailed 9/18/2000 is incorrect.

Applicant asserts that the series of applications describes "Freons" describes the use of the specific gas species' claimed.

This is not found persuasive because the description of a broad genus using generic terminology (i.e., freon) does not show support for specific species' encompassed therein, given the large number of gas species' encompassed thereby. There is no showing that applicant had possession of these specific gases which are broadly encompassed by the term Freon at the time of the claimed priority, let alone, had possession of these specific gas species with any surfactant given that the priority documents only described the use of certain materials as a stabilizer. The concept of using a surfactant for stabilizing the microbubbles in combination with the specific gas species' as claimed was not conveyed in the priority documents, but the claimed combination of a surfactant with the specific gas species' as claimed was

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only described in the instant application, filed March 5, 1999, as set forth in the office action mailed 9/18/2000. There is nothing to show that applicant envisioned the use of these specific gases, as the generic terminology of freon encompasses over 50 specific gases having different chemical structures and properties and such specific gases combined with any stabilizer as now claimed. For species claims to have support, a showing that such species were envisioned is required to show support. See *In re Ruschig*, 15 USPQ 118, CCPA 1967.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 9, 14, 16, 18, 19, 23 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Klaveness '856, Unger '429, Unger '112, Quay '094 and Quay '524, for the reasons set forth in the office action mailed 9/18/2000.

Claims 1-7, 9, 14, 16, 18, 19, 23 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Lohrmann '597, for the reasons set forth in the office action mailed 9/18/2000.

Applicant's arguments filed 1/31/2003 have been fully considered but they are not persuasive.

Applicant asserts that Klaveness '856, Unger '429, Unger '112, Quay '094 and Quay '524 and Lohrmann '597 are not prior art, since applicant is entitled to benefit of priority, to a date prior to the effective filing dates of these patents.

This is not found persuasive, since the actual effective priority date for the instant invention has been determined as March 5, 1999, as set forth in the office action mailed 9/18/2000 and reiterated herein. Thus, the cited references do qualify as prior art for the instantly claimed invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 14, 16, 18, 19, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness '856, Unger '429, Unger '112, Quay '094 and Quay '524, for the reasons set forth in the office action mailed 9/18/2000.

Claims 1-7, 9, 14, 16, 18, 19, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohrmann '597, for the reasons set forth in the office action mailed 9/18/2000.

As stated above, these references do qualify as prior art.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Unger (US 5,088,499), Ryan (US 4,900,540) or Ryan (4,544,545) in view of Tickner (US 4,265,251, for the reasons set forth in the office action mailed 8/7/2002.

Applicant's arguments filed 1/31/2003 have been fully considered but they are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, all the cited art relates to contrast agents comprising gas-filled microparticles. Unger, Ryan '540 and '545 all teach that various gases may be used as equivalents to other known gases, while Tickner teaches that Freon may be used in such contrast agents in an equivalent manner to the gases used by Unger, Ryan '540 and '545. One of ordinary skill in the art would have recognized that various equivalent gases, such as, Freon as taught by Tickner could

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be used in such gas-filled microparticulate contrast agents, given Unger, Ryan '540 and '545 teach that a variety of gases may be employed. Clearly, Tickner provides a teaching that Freon is a gas which is useful for gas-filled contrast agent, (e.g., for ultrasound imaging).

Applicant asserts that the structures used by Unger, Ryan '540 and '545 are completely different from Tickner.

This is not found persuasive because the structures disclosed by Unger, Ryan '540 and '545 and Tickner are not completely different. They both have the same function, to encapsulate a gas and the same use, e.g., for ultrasound imaging. One of ordinary skill in the art would have expected that one microparticle that entraps the same gases as another, e.g., air, etc., would be useful and analogous to another and would be useful to trap equivalent gases. One of ordinary skill in the art would have had a reasonable expectation that the equivalent gases disclosed by Tickner could be entrapped in the microparticles disclosed by Unger, Ryan '540 and '545, since both teach that various and overlapping gases may be contained therein.

Applicant asserts that Unger, Ryan '540 and '545 teach away from modification by teaching that their contrast agents are improvements in the field.

This is not found persuasive. The fact that a reference teaches an improved or superior function does not exclude its use in a rejection based on obviousness under 35 USC 103. In the instant case, the motivation to use other known and useful gases in the inventions of Unger, Ryan '540 and '545 comes by themselves teaches that various gases may be employed in an equivalent manner, while Tickner teaches that Freon is also known to be useful in an equivalent manner for the same purpose. One of ordinary skill in the art would have been motivated to employ any known useful and equivalent gas in the gas-containing contrast agents for ultrasound imaging disclosed by Unger, Ryan '540 and '545.

Applicant asserts that the mere fact that the prior art may be modified does not make the modification obvious unless there is a desirability to make the modification.

Clearly, such desirability exists here. Tickner teaches that Freon is gas which is useful for gas containing microparticles for ultrasound imaging. Unger, Ryan '540 and '545 teach gas-containing microparticles for ultrasound imaging, which may contain various gases as equivalents. Some of the

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gases taught by Unger, Ryan '540 and '545 and Tickner overlap. Clearly, the use of Freon for ultrasound contrast agents is known, as taught by Tickner. One of ordinary skill in the art would have been motivated to use this equivalent and known gas as the gas in such contrast agents, such as those disclosed by Unger, Ryan '540 and '545.

Applicant asserts that the modification cannot change the principle of operation of a reference.

The substitution of one known and equivalent gas for another, given the art teaches that various gases may be used in an equivalent manner does not change the principle of the operation. Further, changing the type of material to encapsulate the gas does not change the principle of operation. The principle of operation in ultrasound contrast agents is trapped gas, which have a greater echogenicity than the solid and liquid tissue surroundings. Clearly, Unger, Ryan '540 and '545 and Tickner show that various shell materials and gases may be used in an equivalent manner to obtain the principle of entrapping gas, without changing any principles of operation.

Applicant asserts that there is no reasonable expectation of success.

This is not found persuasive because there would have been a reasonable expectation of substituting one gas for another. This is shown by the fact that both Unger, Ryan '540 and '545 and Tickner teach the use of various gases, some of which overlap.

Applicant asserts unexpected results.

The unexpected results are not found persuasive. The results are not commensurate in scope with the term surfactant or any gas containing at least one carbon atom and fluorine in combination as claimed. It is noted that the examples cited in the specification to show unexpected results use albumin and a few specifically named gases compared with air. Also, the data does not show a direct comparison between the closest prior art, e.g., the microparticles disclosed by Unger, Ryan '540 and '545 and Tickner.

Double Patenting

Claims 1-7, 9, 14, 16, 18, 19, 23 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. patent Nos. 5,413,774,

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5,578,292, 5,686,060, 5,556,610, 5,445,813, 5,518,991, 5,597,549, 5,567,414, 5,711,933, 5,380,519, 5,531,980, 5,271,928, 5,643,553 and 5,658,551, for the reasons set forth in the office action mailed 7/18/2000.

Applicant's request that this rejection be held in abeyance until the claims are otherwise indicated as being allowable is acknowledged.

Claims 1-7, 9, 14, 16, 18, 19, 23 and 27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending application serial nos. 08/740,653, 08/832,950, 08/637,346, 09/115,963, 08/848,912, 09/021,367, 08/855,055, 08/810,447, 08/910,149, 09/910,152, 08/947,196, 08/893,371, 09/002,710, 09/021,150, 09/225,293, 09/253,536, 09/263,105, 09/401,829, 08/401,835, 08/401,836, 09/401,837 and 09/401,838 for the reasons set forth in the office action mailed 7/18/2000.

Applicant's request that this rejection be held in abeyance until the claims are otherwise indicated as being allowable is acknowledged.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

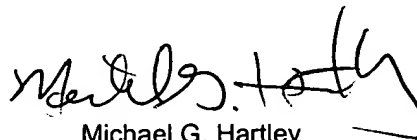
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read "Michael G. Hartley", with a stylized flourish at the end.

Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
February 26, 2003